UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,373	01/03/2006	Mark S. George	19113.0097U2	2026

23859 7590 09/05/2007

NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER	
ABRAHAM, SALIEU M	
ART UNIT	**PAPER NUMBER**
3768	

MAIL DATE	DELIVERY MODE
09/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,373	GEORGE ET AL.	
	Examiner	Art Unit	
	Salieu M. Abraham	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/16/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Reference to Claim 9

The claim recites the following limitation in line 1: "The system of claim 7, wherein **the determining device** obtains a functional brain map of the brain." There is no antecedent basis for "the determining device". It appears that the claim should depend from claim 8.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4 and 8-11) are rejected under 35 U.S.C. 103(a) as being unpatentable over Sean A. Spence (Spence), "Behavioural and functional anatomical correlates of deception in humans". Neuroreport. 12(13):2849-2853, September 17, 2001, in view of US Pat. No. 6,198,958 to Ives (Ives).

In Reference to Claims 1 and 8

Spence teaches a system and method for inhibiting deception, comprising:

- the step of determining at least one region of a brain used for deception and the corresponding device for carrying out the same (see pp. 2850-2851, Table 2 and Fig. 1).

However, Spence fails to teach the method step and corresponding device for "applying magnetic stimulation to the determined region of the brain to inhibit operation of that portion of the brain."

Ives teaches using transcranial magnetic stimulation (TMS) under various diagnostic and therapeutic conditions to stimulate or inhibit areas of brain that correspond to different behavioral and cognitive functions (column 4, lines 37-67, column 5, lines 1-10, and figures 3 and 4).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to add the step and corresponding device for "applying magnetic stimulation to the determined region of the brain to inhibit operation of that portion of the brain" of Ives to the system and method of Spence in order to further facilitate the diagnostic and treatment capabilities of TMS and to more

precisely target the desired/determined region of the brain TMS as expressly taught by Ives (see column 5, lines 8-10).

In Reference to Claims 2 and 9

Spence in view of Ives has been shown to teach all of the claim 1 and 8 limitations respectively. Spence also teaches the method and corresponding system, wherein the step of/device for determining includes obtaining a functional brain map of the brain (see pp. 2850-2851, Table 2 and Figure 1).

Therefore, Spence in view of Ives teaches all claim 2 and 9 limitations.

In Reference to Claims 3 and 10

Spence in view of Ives has been shown to teach all of the claim 2 and 9 limitations respectively. Spence also teaches the method and corresponding system, wherein the functional brain map is obtained using magnetic resonance imaging (see pp. 2850-2851, Table 2 and Figure 1).

Therefore, Spence in view of Ives teaches all claim 3 and 10 limitations.

In Reference to Claims 4 and 11

Spence in view of Ives has been shown to teach all of the claim 1 and 8 limitations respectively. Spence also teaches the method and corresponding system, wherein the functional brain map is obtained using at least one of functional magnetic resonance imaging (fMRI), Positron Emission

Tomography (PET), SPECT, qEEG, and MEG. (see pp. 2850-2851, Table 2 and Figure 1).

Therefore, Spence in view of Ives teaches all claim 4 and 11 limitations.

5. Claims 5, 6, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence in view of Ives further in view of C.M. Epstein (Epstein), "Repetitive transcranial magnetic stimulation does not replicate the Wada test." Neurology. 2000;55: 1025-1027.

In Reference to Claims 5 and 12

Spence in view of Ives has been shown to teach all of the claim 1 and 8 limitations respectively. However, **Spence** in view of Ives fails to teach the method and corresponding system "wherein the magnetic stimulation is applied to the determined portion of the brain of an individual while the individual is speaking."

Epstein teaches applying TMS to a predetermined region of the brain while the subject is speaking in order to control and characterize individual speech and language (see abstract and p.1025). Epstein goes on to compare results from his TMS studies with a popular (Wada) test used to assess and reproducibly control speech and language function (i.e. whether inhibited or not) in neurology (see first four paragraphs on page 1025).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the protocol (apparatus and method) of Epstein in the

system and method of Spence in view of Ives in order to manage and determine whether and to what degree control of speech is associated with a known speech region in the brain as explicitly taught by Epstein (see abstract and paragraph 4).

In Reference to Claims 6 and 13

Spence in view of Ives further in view of Epstein has been shown to teach all of the claim 5 and 12 limitations respectively. **Epstein** further teaches the method and corresponding system "wherein the application of the magnetic stimulation prevents the individual from telling a lie" (see page 1025, paragraph 4; especially section regarding complete speech arrest<SA>) by preventing any or intelligible speech. **Therefore,** Spence in view of Ives further in view of Epstein teaches all claim 6 and 13 limitations.

6. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence in view of Ives further in view of Hugo D. Critchley (Critchley), "Neural Activity Relating to Generation and Representation of Galvanic Skin Conductance Responses: A Functional Magnetic Resonance imaging Study." Journal of Neuroscience, April 15, 2000; 20(8): 3033-3040.

In Reference to Claims 7 and 14

Spence in view of Ives has been shown to teach all of the claim 1 and 8 limitations respectively. However, **Spence** in view of Ives fails to teach the method and

corresponding system "further comprising measuring physiological and electrodermal activity of the individual for verifying, correlating and/or enhancing results determined by the step of determining.

Critchley teaches a method and corresponding system employing functional MRI (fMRI) and skin conductance protocols (see materials and methods on page 3034) for measuring the physiological and electrodermal activity of an individual subject (see abstract and pages 3033 and 3034). The study focused on correlating electrodermal activity, also referred to as skin conductance response (SCR), with regional brain activity in order to better understand the "central regulation and representation of SCR" (see page 3033, first paragraph). Critchley further cites that it is known in the art to use SCR in conjunction with fMRI to investigate behavioral and cognitive neural activity and that there is a positive correlation between these (SCR/fMRI measurements and cognitive and behavioral neuronal activity; see page 3033).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included an SCR with fMRI protocol as taught by Critchley in the system and method of Spence as an additional measure for tracking neuronal activity and resulting behavior associated with deception inhibition as taught by Critchley (see pages 3033, and top paragraph on page 1034).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Abrams et al., Blazey et al., Epstein et. al., Firlik et. al., Fox et.

al., Ives et. al, Kuth., Rohan et. al., Tanner, and Young have been included because they all teach the utilization of various systems and methods for the management and evaluation of behavioral and cognitive-related neuronal activity in the brain similar to applicant's proposed invention.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 9:30 am - 7:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8/2/07 SA

ELENI MANTIS MERCADER
SPE 3768